510(K) SUMMARY K071545

Zyno Medical LLC.
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Contact Person:

Chaoyoung Lee
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Date Prepared: May 1, 2007

Trade Name: Z-800 Infusion Pump
Common Name: Volumetric Infusion Pump
Classification Name: Infusion Pump

Predicate Devices
B.Braun Vista basic, Sigma 8000, Abbott Acclaim Encore

Intended Use

The Z-800 Infusion pump is intended to provide accurate delivery of parenteral fluids to a human patient under the direction or supervision of physician or other certified health care professional.

Device Description:

Z-800 Premarket Notification – 1 May 2007, Revised per FDA Review October 17, 2007

The Z-800 Infusion pump is intended to provide accurate delivery of parenteral fluids to a human patient under the direction or supervision of physician or other certified health care professional.

The infusion pump contains the following hardware assemblies: Linear peristaltic pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, and electronics assembly. The power supply cord can be plugged and removed from the receptacle in the rear of the pump. The battery power supply consists of rechargeable 12 volt battery pack. The user interface subassembly contains and dot matrix LCD display, and a keypad used to input data into the pump as well as to present pump status and information to the user.

The electronics subassembly contains all of the electronics in the pump, including the microprocessors that run the software. The electronics subassembly also contains communications electronics that will allow the pump to transmit and receive messages to and from external devices, including personal computers and hospital information systems.

The pump has two microprocessors, one master processor which controls operation of the device, another pump processor which controls the operation of the motor and sensors specific to the peristaltic pumping mechanism.

Equivalency Matrix

Parameter	Z-800	B. Braun Vista basic	Sigma 8000	Abbott Acclaim Encore
Pump Type	Volumetric Infusion Pump	Volumetric Infusion Pump	Volumetric Infusion Pump	Volumetric Infusion Pump
Intended use	Intra-venous	Intra-venous	Intravenous Epidural	Introvenous

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

Mr. Chaoyoung Lee
President
Zyno Medical LLC
395 Totten Pond Road, Suite 201
Waltham, Massachusetts 02451

Re: K071545
Trade/Device Name: Z-800 Volumetric Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 22, 2007
Received: October 22, 2007

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

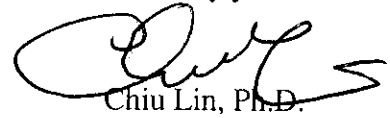
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071545

Device Name: Z-800 Volumetric Infusion Pump

Indications for Use: The Z-800 Infusion pump is intended to provide accurate delivery of parenteral fluids to a human patient under the direction or supervision of physician or other certified health care professional.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ivision Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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